Remarks

This Communication is in response to the Final Office Action dated **June 16, 2010.** The Office Action rejected claims 1, 92-94, and 98-101 under 35 USC § 102(e) over Richter (US 6,315,794); rejected claims 1, 91, 95, 100, 101, 108-110, 114, 119, and 120 under 35 USC § 102(b) over Venbrux (US 5,443,497); rejected claims 1, 91, 92, 94, and 98-101 under 35 USC § 102(e) over Kranz (US 6,312,456); rejected claims 1, 91, 92, 94, 96-100, 108-111, 113, and 115-119 under 35 USC § 103(a) over Scott (US 5,383,928) in view of Myers (US 5,700,285); and rejected claims 1, 91-101, and 105-123 under 35 USC § 103(a) over Berg (US 5,464,650) in view of Scott, Nolting (US6,488,701), and Jang (US Pub. No. 2004/0106985).

In light of the following comments, Applicant requests reconsideration.

Claim Rejections – Section 102

Claims 1, 92-94, and 98-101 over Richter

In rejecting claims 1, 92-94, and 98-101 under 35 USC § 102(e), the Office Action asserts:

> Richter disclose an expandable stent (fig 3A) comprising a coating of a drug on the stent ends wherein the middle is free of the drug. The coating 202 comprises a metallic material which is encompassed by the broadly claimed "drug", and in view of the broad definition afforded the term in the specification at paragraph [0050] of the published application (note line 2 "or for other treatments" and the final line).

Applicant disagrees and the rejection is *traversed*.

The radiopaque material of Richter is not a "drug" as claimed. Paragraph [0050] of the immediate Application, referenced in the Office Action, states, in-part, "[t[he coating 18 may also be used as a drug delivery system to prevent restenosis or for other treatment. The drugs may include radiochemicals to irradiate and prohibit tissue ingrowth."

Richter discloses a "multilayered metal stent." Title of Richter. In an embodiment of Richter, the metal stent has a "[s]econd coating 202 [that] comprises a suitable radiopaque material such as gold, platinum, silver, and tantalum . . . ." Column 4, lines 65-66. *See also* FIGs. 3A and 3B of Richter, below.

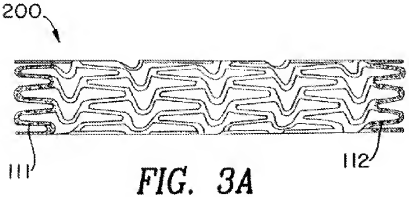


FIG. 3A

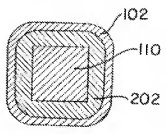


FIG. 3B

The Office Action's assertion that the claimed term "drug" can be read to include the radiopaque coating (gold, platinum, silver, and tantalum) disclosed in Richter is erroneous. While the Office Action can properly assert the broadest reasonable interpretation of a term in light of the specification, the interpretation proposed in the Office Action is simply not reasonable. The Office Action essentially alleges that the specification has defined the term "drug" so broadly as to encompass any and all materials. By the logic of the Office Action, a metal stent itself could be a drug in that it is used to "treat" a patient. This approach is unreasonable. One of ordinary skill in the art simply would not regard the radiopaque coatings of Richter as "drugs."

With regard to the Office Action's assertion, on page 2, that the phrase '[o]ther treatment…' may be considered "an imaging treatment or the mere expansion of the stent whereby the gold coating assists the delivery and expansion of the stent," the Office Action has misinterpreted this phrase. The Office Action uses the phrase "other treatment" as applying to the device. In other words, the Office Action appears to consider the "other treatment" to include "an imaging treatment" or a treatment of gold coating that "assists the delivery and expansion of the stent." In contrast, the "treatment" discussed in Applicant's Specification with respect to the claimed "drug" is used to refer to the treatment of the patient. Therefore, the Office Action's reliance on the phrase "or other treatment" is misplaced.

Moreover, the phrase "or other treatments" in paragraph [0050] of Applicant's Specification does not transform the metallic radiopaque coatings of Richter into "drugs" as claimed. The radiopaque coatings identified in Richter are used for the purpose of providing improved fluoroscopic characteristics while retaining desirable mechanical properties. *See* column 3, lines 11-24. Instead, the drugs of the immediate application are provided, for example, to

"prevent restenosis or for other treatment." Paragraph [0050]. Consequently, as will be appreciated by one of ordinary skill in the art, the "drugs" of the immediate application are applied to the device so that the drug can treat the patient, for example by preventing restenosis. In contrast, the radiopaque coatings of Richter are merely used to view the device during fluoroscopic procedures. As such, one of ordinary skill in the art would not characterize the radiopaque coatings of Richter as "drugs." *See e.g.*, MPEP § 2111.01 (words of a claim must be given their plan meaning – "the meaning that the term would have to a person of ordinary skill in the art . . . .") (internal citations omitted).

Furthermore, the Office Action's assertion that "'[o]ther treatment' may be considered an imaging treatment or the mere expansion of the stent whereby the gold coating assists the delivery and expansion of the stent," appears to equate a "drug" with any coating placed on and expanding with a stent. The Office Action's assertion is untenable. Paragraph [0055] of the immediate Application states, in-part, "the stent can have two layers of the same polymer coating 18 with one layer with drug and another layer without drugs." (Emphasis added). This phrase of the immediate Application therefore assumes that not all coatings are, or contain, drugs. Indeed, the fact that a coating can be provided without a drug necessitates the conclusion that not all coatings are drugs and not all coatings contain drugs. Consequently, the Office Action's assertion that a drug is an "other treatment," including "the mere expansion of the stent whereby the gold coating assists the delivery and expansion of the stent," is contradicted by the language of the immediate specification. The term "drug" is not so broad as to encompass a radiopaque coating added to a stent.

In light of the foregoing, the Office Action's assertion that the radiopaque materials of Richter can be considered "drugs" is erroneous and Applicant requests withdrawal of the rejection of independent claim 1 and dependent claims 92-94 and 98-101.

Claims 1, 91, 95, 100, 101, 108-110, 114, 119, and 120 over Venbrux

In rejecting claims 1, 91, 95, 100, 101, 108-110, 114, 119, and 120 over Venbrux (shown below) the Office Action asserts:

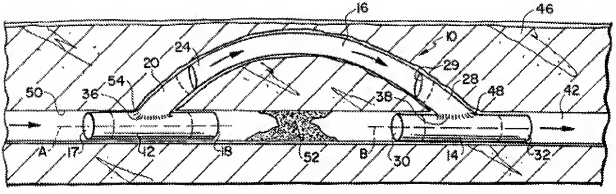
> stent 12 may be considered to comprise first end portion 20 having a coating and ePTFE tube 16 sewn thereto, middle portion 18, and second end portion 17. . . . [T]he claims recite "end portions" whereby the portion may be considered the

terminal end 17,18 or a region spaced from the terminal end such as the region denoted 20 in Figure 1.

Page 3. The Office Action further asserts, on page 5:

> Venbrux disclose in figure 1 an expandable stent (12 or 14) comprising an end portion having a coating thereon of adhesive or other polymer wherein the middle portion 16 is free of the coating. The coating may be sewn through to attach stent 16 such that apertures/perforations exist. See columns 2-3.

FIG. 1



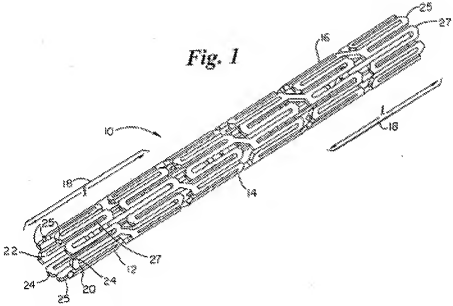
The Office Action's rejections over Venbrux are *traversed*. It is unclear whether the Office Action regards the claimed "middle portion" as reference numeral 16 of Venbrux or reference numeral 18. As noted above, on page 2 the Office Action refers to "middle portion 18." Subsequently, on page 2, the Office Action states, "the claims recite 'end portions' whereby the portion may be considered the terminal end 17,18 or a region spaced form the terminal end . . . ." Then, on page 5, the Office Action refers to "middle portion 16." Venbrux refers to reference numeral 18 as "an outlet 18," column 2, line 54, and refers to reference numeral 16 as "tubular central member 16." Column 3, line 30. In light of these seemingly conflicting assertions, it is unclear what structure of Venbrux is believed to be the claimed "middle portion." In addition, and as discussed in Applicant's previous response of December 4, 2009, Venbrux simply does not disclose what is claimed in independent claims 1, 108, and 109. For example, independent claim 1 recites, in-part:

> a first biocompatible coating adhered directly on at least the metal outer surface of the first end portion of the main body portion, wherein the first

biocompatible coating comprises a polymer or a drug contacting the metal outer surface, and wherein the metal outer surface and the metal inner surface of the middle portion are free of the polymer or drug.

The Office Action's assertion that the "outlet 18" of Venbrux can be referred to as Applicant's claimed "middle portion," is erroneous. MPEP § 2111.01 requires that the words of a claim be given their 'plain meaning' unless it is inconsistent with the specification. Moreover, the plain meaning is that given by one of ordinary skill in the art. *Id.* One of ordinary skill in the art would not interpret the "outlet 18" of Venbrux to be Applicant's claimed "middle portion." For example, as shown below in Fig. 1 of the immediate application, the "middle portion" is illustrated at reference numeral 14. *E.g.*, paragraph [0032] of the Published Application.

Fig. 1



Therefore, neither Venbrux nor the immediate Application supports the Office Action's assertion that the "outlet 18" of Venbrux can be referred to as the claimed "middle portion." The "outlet 18" of Venbrux is disposed at an end of the proximal stent 12, not on a "middle portion."

In light of the foregoing, Venbrux does not disclose what is claimed in independent claims 1, 108, and 109, and Applicant requests withdrawal of the rejections thereof. Moreover, Applicant further requests withdrawal of the rejections of dependent claims 91, 95, 100, 101, 110, 114, 119, and 120, which depend from claims 1 and 109, respectively.

Claims 1, 91, 92, 94, and 98-101 over Kranz

The Office Action's rejection of claims 1, 91, 92, 94, and 98-101 under 35 USC § 102(e) over Kranz is *traversed*. In rejecting these claims over Kranz, the Office Action asserts, "[t]he coating 4 [of Kranz] comprises a metallic material which is encompassed by the broadly claimed "drug", and in view of the broad definition afforded the term in the specification at paragraph [0050] of the published application (not line 2 "or for other treatments" and the final line)." Page 5.

Kranz discloses a "biocompatible stent with radiopaque markers." Title of Kranz. Kranz fails to disclose the subject matter of independent claim 1, for essentially the same reasons as discussed above with respect to Richter. In particular, Kranz discloses "[o]n its two ends 11a and 11b, the hollow cylinder 1A respectively comprises one welded-on thread 5a or 5b, configured in a meandering shape and made of a tantalum alloy." Column 3, lines 46-48. *See also* FIG. 1 of Kranz, below. Kranz further notes that gold and silver can be used as X-ray opaque materials. Column 3, lines 32-34.

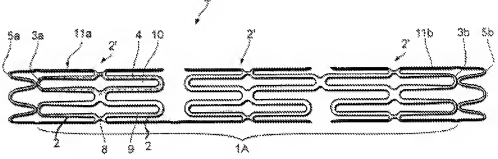


Fig.1

Kranz fails to disclose a "biocompatible coating compris[ing] a polymer or a drug . . ." as is claimed, for example, in independent claim 1. The X-ray opaque materials of Kranz are simply not drugs or polymers, as claimed, and one of ordinary skill in the art would not regard them as such. Consequently, Applicant requests withdrawal of the rejection of claims 1, 91, 92, 94, and 98-101 over Kranz.

Claim Rejections – Section 103

Claims 1, 91, 92, 94, 96-100, 108-111, 113, and 115-119 over Scott in view of Myers

The Office Action's rejection of claims 1, 91, 92, 94, 96-100, 108-111, 113, and

115-119 under 35 USC § 103(a) over Scott in view of Myers is *traversed*.

In rejecting independent claims 1, 108, and 109 over Scott in view of Myers, on pages 6-7, the Office Action asserts:

> Scott is silent as to directly adhering the sleeve coating material to the metal surface of the stent. Myers teach stents with sleeve coatings wherein the material may be affixed to the stent by thermoplastic adhesive and the coatings remained intact after collapsing and enlarging the stent (see abstract and examples). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent in Scott to include adhesion points, as taught in Myers, to secure the sleeve position and prevent migration of the sleeve from the stent.

At column 4, lines 1-14, Scott states, in-part:

> Unfortunately, Biogold and other coated stents have not completely prevented arterial thrombosis. This is probably related to the cracking of the polymer as the stent is expanded during deployment, saturation of the anticoagulant binding sites on the stent, and/or inadequacy of heparin as an anticoagulant in the prevention of arterial thrombosis.
>
> Because of the inadequacies associated with polymer coatings directly applied onto the stent wires, there remains a great need to effectively prevent thrombosis at the stent site. The present invention satisfies this need by providing a separate sleeve to encompass the stent and serve as a local drug delivery device to prevent thrombosis.

Scott therefore teaches away from using a coating, and instead proposes using a "separate sleeve to encompass the stent . . . ." *Id* at line 12. The Office Action seems to recognize the distinction between the "separate sleeve" disclosed in Scott and a coating, stating, on page 3 of the Office Action, "[i]t is further noted that Scott makes a distinction between a sleeve and a coating that is dipped or covalently bound directly to the stent." The Office Action nonetheless asserts that "a sleeve meets the broadest reasonable interpretation of a coating as claimed," *id*, because "[a] coating is defined as a material covering a substrate."

Applicant disagrees. The Office Action's definition of a "coating" is overly broad and the Office Action has cited no precedent for the "definition" proposed. Indeed, although the Office Action attempts to shoehorn the "sleeve" of Scott into the definition of coating by

providing an overly broad definition of "coating," as noted above, Scott distinguishes between a sleeve and a coating. *See e.g.*, column 4, lines 1-14.

Moreover, Myers does not cure this deficiency of Scott. Myers discloses, "a tubular intraluminal graft in the form of a tubular diametrically adjustable stent having a tubular covering of porous expanded polytetrafluoroethylene . . . . The covering may be affixed to the stent by an adhesive . . . ."

Therefore, neither Scott nor Myers discloses a coating as claimed and Applicant requests withdrawal of the rejection of claims 1, 91, 92, 94, 96-100, 108-111, 113, and 115-119 over Scott in view of Myers

Claims 1, 91-101, and 105-123 over Berg, Scott, Nolting, and Jang

The rejection of claims 1, 91-101, and 105-123 over Berg in view of Scott, Nolting, and Jang is *traversed*. In rejecting claims 1, 91-101, and 105-123 over Berg in view of Scott, Nolting, and Jang, and in response to the arguments presented in Applicant's response of December 4, 2010, on pages 3-4, the Office Action asserts:

> With respect to the 103 rejection over Berg in view of Scott, Nolting, and Jang, Applicant argues that Scott teaches away from coatings and thus any teachings flowing from Scott could not be combined with a coated stent such as Berg. This is not persuasive, as Scott teaches the concept of delivering drugs from a polymer substrate located all over a stent or only over a portion of a stent (i.e. a proximally located ring). In other words, Scott teaches the discovery that localized delivery of a drug requires less drug and imparts less systemic delivery of the drug. These teachings would have been clearly recognized as applicable to dip-coated or spray coated stents.
>
> Furthermore, Scott teaches that prior coatings "cracked" upon expansion. The coating in Berg is improved and is flexible to expand with the stent, and is thus apparently different from the methods Scott might be considered to teach away from.

The Office Action has mischaracterized the disclosure of Scott. The Office Action's assertion that "Scott teaches the discovery that localized delivery of a drug requires less drug and imparts less systemic delivery of the drug," is overly broad. As noted above, Scott

discloses, "a separate sleeve to encompass the stent and serve as a local drug delivery device to prevent thrombosis." Column 4, lines 12-14.

Furthermore, the Office Action's assertion that "Scott teaches the concept of delivering drugs from a polymer substrate . . ." is also overly broad. Scott discloses that "[b]ecause of the inadequacies associated with polymer coatings directly applied onto the stent wires, there remains a great need to effectively prevent thrombosis at the stent site." *Id* at lines 8-11. Therefore, the Office Action has mischaracterized the disclosure of Scott.

In addition, the Office Action has provided no support for the assertion that "[t]he coating of Berg is improved and is flexible to expand with the stent . . . ." Moreover, and for the sake of argument only, even if the device of Berg is "improved," the Office Action has not shown that the "improved" coating of Berg does not suffer from certain problems identified in the Background section of the Scott patent. And, although Berg indicates that "[i]t is also an object of the present invention to provide a stent which may be delivered and expanded in a selected blood vessel without losing a therapeutically significant amount of a drug applied thereto," column 2, lines 16-19, it is unclear why one of ordinary skill in the art would be motivated to modify Berg in lieu of merely using the sleeve of Scott.

For at least the foregoing reasons, the Office Action has failed to establish a *prima facie* case of obviousness. One of ordinary skill in the art would not be motivated to modify the stent of Berg with Scott, as the Office Action suggests. Instead, the skilled artisan would be expected to ignore the coating of Berg in lieu of the sleeve of Scott.

With regard to the Nolting reference, the arguments presented in Applicant's previous response of December 4, 2009, are herein incorporated by reference. In particular, as discussed on pages 13-14 of Applicant's previous response, "[m]odifying the stent of Berg with the disclosure of Nolting would not produce a stent wherein the metal outer surface and metal inner surface of the middle portion are free of any coating comprising a polymer or drug."

Consequently, Applicant requests withdrawal of the rejection of claims 1, 91-101, and 105-123 over Berg, Scott, Nolting, and Jang.

Conclusion

Based on at least the foregoing remarks, Applicant requests allowance of claims 1, 91-101, and 105-123. Favorable consideration and prompt allowance of these claims is earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance the Examiner is invited to contact Applicant's undersigned representative at the telephone number listed below.

Respectfully submitted,

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